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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,790	11/12/2003	Gerald B. Pier	B0801.70255US01	5867

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EXAMINER	
DEVI, SARVAMANGALA J N	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
06/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/713,790	PIER ET AL.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-25,42 and 86-98* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-25,42 and 86-98* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *123107 & 062907*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

RESPONSE TO APPLICANTS' AMENDMENT

Applicants' Amendment

1) Acknowledgment is made of Applicants' amendment filed 11/19/07 in response to the non-final Office Action mailed 05/15/07.

Status of Claims

2) Claims 82-85 have been canceled via the amendment filed 11/19/07.

Claims 1, 2, 4, 5, 9, 12-15, 21, 23 and 24 have been amended via the amendment filed 11/19/07.

New claims 86-98 have been added via the amendment filed 11/19/07.

Claims 1, 2, 4-25, 42 and 86-98 are pending and are under examination.

Information Disclosure Statements

3) Acknowledgment is made of Applicants' information disclosure statements filed 12/31/07 and 06/29/07. The information referred to therein has been considered and a signed copy is attached to this Office Action.

Prior Citation of References

4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Objection(s) Withdrawn

5) The objection to claim 9 made in paragraph 28 of the Office Action mailed 05/15/07 is withdrawn in light of Applicants' amendment to the claim.

Rejection(s) Withdrawn

6) The provisional rejection of claims 1, 2, 6, 8, 9, 11, 14, 19 and 20 made in paragraph 24 of the Office Action mailed 05/15/07 under the judicially created doctrine of obviousness-type double patenting over claim 63 of the co-pending

application 09/771,003, is withdrawn in light of the issuance of application 09/771,003 and Applicants' amendment to the claims and/or the base claim(s).

7) The provisional rejection of claim 18 made in paragraph 24 of the Office Action mailed 05/15/07 under the judicially created doctrine of obviousness-type double patenting over claim 67 of the co-pending application 09/771,003, is withdrawn in light of the issuance of application 09/771,003 and Applicants' amendment to the claims and/or the base claim(s).

8) The rejection of claims 16 and 17 made in paragraph 25(a) of the Office Action mailed 05/15/07 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to claim 15.

9) The rejection of claims 1 and 2 made in paragraph 25(b) of the Office Action mailed 05/15/07 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claims.

10) The rejection of claim 2 made in paragraph 25(c) of the Office Action mailed 05/15/07 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

11) The rejection of claim 23 made in paragraph 25(e) of the Office Action mailed 05/15/07 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

12) The rejection of claim 23 made in paragraph 25(f) of the Office Action mailed 05/15/07 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

13) The rejection of claim 23 made in paragraph 25(g) of the Office Action mailed 05/15/07 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

14) The rejection of claim 21 made in paragraph 25(h) of the Office Action mailed 05/15/07 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

15) The rejection of claim 14 made in paragraph 25(i) of the Office Action mailed 05/15/07 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

16) The rejection of claims 1 and 2 made in paragraph 25(j) of the Office Action mailed 05/15/07 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

17) The rejection of claims 4-25 and 42 made in paragraph 25(j) of the Office Action mailed 05/15/07 under 35 U.S.C. § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the base claim.

18) The rejection of claims 1, 2, 4-16, 18-24 and 42 made in paragraph 26 of the Office Action mailed 05/15/07 under 35 U.S.C § 102(b) as being anticipated by McKenney *et al.* (*Infect. Immun.* 66: 4711-4720, October 1998 - Applicants' IDS) (McKenney *et al.*, 1998) as evidenced by Joyce *et al.* (*Carbohydr. Res.* 338: 903-922, 2003), McKenney *et al.* (*J. Biotechnol.* 83: 37-44, 2000 - Applicants' IDS) (McKenney *et al.*, 2000), and Maira-Litran *et al.* (*Infect. Immun.* 73: 6752-6762, 2005), is withdrawn in light of Applicants' amendment to the claims and/or the base claim(s). Applicants' arguments have been considered, but are moot in light of the new rejection set forth below to address the claims, as amended.

19) The rejection of claims 17 and 25 made in paragraph 27 of the Office Action mailed 05/15/07 under 35 U.S.C § 103(a) as being unpatentable over McKenney *et al.* (*Infect. Immun.* 66: 4711-4720, October 1998 - Applicants' IDS) (McKenney *et al.*, 1998) as applied to claims 15, 1, 22 and 21 above, and further in view of Pier *et*

al. (US 20020119166 – Applicants' IDS), is withdrawn in light of Applicants' amendment to the base claim(s). Applicants' arguments have been considered, but are moot in light of the new rejection set forth below.

Rejection(s) Maintained

20) The rejection of claim 42 made in paragraph 25(d) of the Office Action mailed 05/15/07 under 35 U.S.C. § 112, second paragraph, as being indefinite, is maintained for reasons set forth therein and herein below.

Applicants cite MPEP 706.03(d) which states that this form paragraph should only be used in aggravated situations where the lack of antecedent basis makes the scope of the claim indeterminate. Applicants contend that this is not the situation since claim 42 refers to the isolated polysaccharide which is defined in claim 1 from which claim 42 depends. Applicants cite MPEP 2173.02 and assert that definitiveness of claim language must be analyzed, not in a vacuum, but in light of: (a) The content of the particular application disclosure; (b) The teachings of the prior art; (c) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. Applicants conclude that one of ordinary skill in the art would understand claim 42 to recite a pharmaceutical composition that comprises the isolated polysaccharide as defined in claim 1.

Applicants' arguments have been carefully considered, but are not persuasive. Claim 42 continues to be indefinite. Claim 1, from which claim 42 depends, is not drawn to 'an isolated polysaccharide', but to '[a] composition comprising an isolated polysaccharide'. The two are not of same scope. The limitation 'composition comprising' in claim 1 includes the recited isolated polysaccharide and any other elements including a carrier, an adjuvant, a protein

etc. An isolated polysaccharide is just one component comprised within the composition of claim 1. The composition of claim 1 does not exclude, but encompasses a pharmaceutical composition. It is suggested that Applicants rephrase claim 42 to recite --The composition of claim 1, wherein said composition is a pharmaceutical composition comprises the isolated polysaccharide in an amount effective to stimulate an immune response in a subject in a pharmaceutically acceptable carrier.--

New Rejection(s) Necessitated by Applicants' Amendment

Double Patenting Rejection(s)

21) Claims 1, 2, 4-25, 42 and 86-98 are rejected under the judicially created doctrine of obviousness-type double patenting over claim 1 of US patent 7,252,828 (Applicants' IDS) ('828) in view of Fattom *et al.* (*Infect. Immun.* 66: 4588-4592, 1998). Claim 18 is rejected under the judicially created doctrine of obviousness-type double patenting over claims 9-11 of US patent 7,252,828 in view of Fattom *et al.* (*Infect. Immun.* 66: 4588-4592, 1998). Instant claims are directed to an invention not patentably distinct from the above-identified claims of commonly assigned '828 patent. Specifically, the product of claims 1-3 and 9-11 of the above-identified patent falls within the scope of the above-identified claims except for the percent of glucosamine amino groups being substituted with acetate. The portions of the disclosure from the '828 patent that provide support for the isolated PS/A polysaccharide composition having a molecular weight of >100,000 Daltons and being greater than 92% pure as claimed, do not exclude, but expressly encompass an isolated sterile beta-1,6-glucosamine polymer composition differing in the degree of acetate substitution between 50% and 100%. The portions of the disclosure from the '828 patent that provide support for the isolated PS/A polysaccharide composition

taught the integer n to be 3-6, 3-20, or equal to or grater than 490; the molecular weight to be between 100,000 and 5,000,000; the carrier compound linked to the PS/A to be a peptide or protein; and the composition to be sterile. The structure of the polymer is identical to the instantly recited polymer except for the percent of glucosamine amino groups in the substituted with acetate. See the structures disclosed in columns 3 and 5; and third full paragraph in column 4; columns 3-5; and paragraph bridging columns 9 and 10; paragraph bridging columns 2 and 3, 3 and 4, and 9 and 10; first full paragraph in column 24; third full paragraph in column 3; and second full paragraph in column 14.

The '828 patent does not expressly state that less than 50%, 45%, or 40% of glucosamine amino groups in the composition of their purified PS/A polysaccharide are substituted with acetate, although the patent taught that the extent of acetylation of the PS/A (poly beta-1,6-glucosamine) varies depending on the growth conditions.

However, it was routine and conventional in the art of acetylated staphylococcal polysaccharides to deacetylate an acetylated staphylococcal polysaccharide to study or determine the presence of immunological determinants therein. For example, Fattom *et al.* taught deacetylation of a highly acetylated staphylococcal polysaccharide by incubation at 37°C with NaOH to produce the polysaccharide backbone before using the backbone (i.e., the deacetylated polysaccharide) to determine the presence of backbone determinants. See abstract; and pages 4588 and 4591.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to deacetylate the '828 patent's acetylated poly beta-1,6-glucosamine to produce the instant invention with a reasonable expectation of success. Given that it was routine and conventional in the art to deacetylate an

acetylated staphylococcal polysaccharide to make available or expose the immunodeterminants on the polysaccharide backbone as taught by Fattom *et al.*, one of ordinary skill in the art would have been motivated to produce the instant invention for the expected benefit of identifying the immunodeterminants on the backbone of the '828 patent's acetylated poly beta-1,6-glucosamine PS/A.

Rejection(s) under 35 U.S.C § 112, Second Paragraph

22) The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his/her invention.

23) Claims 1, 2, 4-20, 87, 90 and 91 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claims 1 and 2 are vague in the limitation: 'amino groups in the composition'. Are these amino groups a part of the recited isolated polysaccharide, or a part of any other element(s) 'comprised' in the composition?

(b) Claim 87 is indefinite because it is not further limiting or is improperly broadening in scope. Claim 87 depends from claim 86 wherein the polysaccharide has a structure that is limited, among other features, to X6 and Y2 as recited. However, the polysaccharide recited in the dependent claim 87 leaves these two positions open to anything including those other than X6 and Y2.

(c) Claims 4-20, which depend from claim 1 or 2, and claims 90 and 91, which depend from claim 87, are also rejected as being indefinite because of the indefiniteness identified above in the base claim.

Rejection(s) under 35 U.S.C § 102

24) The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office Action:

> A person shall be entitled to a patent unless –
> **(b)** the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

25) Claims 1, 2, 4-16, 18-24, 42 and 86-97 are rejected under 35 U.S.C § 102(b) as being anticipated by McKenney *et al.* (*Infect. Immun.* 66: 4711-4720, October 1998 - Applicants' IDS) (McKenney *et al.*, 1998).

McKenney *et al.* (1998) taught a PS/A composition (i.e., vaccine) comprising or consisting of an isolated and purified large molecular weight beta-1,6-glucosamine polysaccharide substituted with 0 to 33% acetate. The composition further contains phosphate buffered saline (i.e., pharmaceutically acceptable carrier) and is filter-sterilized. The polysaccharide contained glucosamine as the single sugar component, and therefore is expected to be at least 90% pure. McKenney *et al.* (1998) expressly taught that different lots of PS/A produced from the same strain, *S. epidermidis* M187, showed variation in the acetate level from **0 to 33%** substitution of the glucosamine residues (i.e., less than 50%, 45%, 40%, 35%, 30%, 25%, 20%, 15%, 10% or 5%). See first full paragraph on page 4714; and paragraph bridging pages 4712 and 4713. Thus, at least one of the different lots of PS/A produced from *S. epidermidis* strain M187 had the acetate level of 0% or 33% substitution of the glucosamine residues, or a percent substitution in between. The molecular weight of the polysaccharide is >250,000 kDa, and therefore would be expected to contain at least four monomeric units of the structure recited, wherein n is at least 6, wherein X1, X2, X3, X4, X5 and X6 is H, and Y1, Y2 and Y3 is OH, wherein one of the X1, X2, X3, X4, X5 or X6, or Y1, Y2 or Y3 in the monomeric units is conjugated to the adjacent saccharide unit(s), i.e., a carrier compound. See abstract.

Claims 1, 2, 4-16, 18-24, 42 and 86-97 are anticipated by McKenney *et al.*

Rejection(s) under 35 U.S.C § 103

26) The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> **(a)** A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person. having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 148 USPQ 459, that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or unobviousness.

27) Claims 17, 25 and 98 are rejected under 35 U.S.C § 103(a) as being unpatentable over McKenney *et al.* (*Infect. Immun.* 66: 4711-4720, October 1998 - Applicants' IDS) (McKenney *et al.*, 1998) as applied to claims 15, 1, 22 and 21 above, and further in view of Pier *et al.* (US 20020119166 – Applicants' IDS).

The teachings of reference of Pier *et al.* is applied in this rejection because it qualifies as prior art under subsection (e) or (a) of 35 U.S.C. § 102 and accordingly is not disqualified under U.S.C. 103(a).

The teachings of McKenney *et al.* (1998) are explained above which do not expressly disclose that the at least four monomeric beta-1,6-glucosamine polysaccharide is conjugated to a carrier compound that is not an N-acetyl beta 1-6 glucosamine such as a peptide carrier or protein carrier.

However, conjugating an isolated staphylococcal poly-beta-1-6-N-acetylglucosamine to a carrier compound including a carrier protein such as BSA or KLH, a peptide, or a lipid, using conjugation methods well known in the art was

routine and conventional in the art at the time of invention for the purpose of enhancing its immunogenicity in a species of animal to be immunized. For example, see sections [0028], [0085], [0086], and [0089] of Pier *et al.*

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to conjugate McKenney's (1998) isolated and purified beta-1,6-glucosamine polysaccharide to an art-known carrier protein such as KLH, BSA, or a peptide using an art-known conjugation technique as taught by Pier *et al.* to produce the instant invention with a reasonable expectation of success. One of ordinary skill in the art would have been motivated to produce the instant invention for the expected benefit of enhancing the immunogenicity of McKenney's (1998) isolated and purified beta-1,6-glucosamine polysaccharide in a species of animal to be immunized as taught by Pier *et al.*

Claims 17, 25 and 98 are *prima facie* obvious over the prior art of record.

28) Claims 1, 2, 4-25, 42 and 86-98 are rejected under 35 U.S.C. 103(a) as being obvious over US patent 7,252,828 (Applicants' IDS) ('828) in view of Fattom *et al.* (*Infect. Immun.* 66: 4588-4592, 1998).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130

stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The '828 patent disclosed an isolated PS/A polysaccharide composition having a molecular weight of >100,000 Daltons and being greater than 92% pure as claimed, do not exclude, but expressly encompass an isolated sterile beta-1,6-glucosamine polymer composition differing in the degree of acetate substitution between 50% and 100%. The integer n is 3-6, 3-20, or equal to or grater than 490. The structure of the polymer is identical to the instantly recited polymer except for the percent of glucosamine amino groups in the substituted with acetate. See claims 1-3, 9-11; the structures disclosed in columns 3 and 5; and third full paragraph in column 4; columns 3-5; and paragraph bridging columns 9 and 10. The polysaccharide composition is sterile and comprises a pharmaceutically acceptable carrier. See first full paragraph in column 24. The PS/A composition id formulated as a vaccine. See third full paragraph in column 3. The PS/A is conjugated to a carrier compound such as a peptide or a protein carrier. See second full paragraph in column 14.

The '828 patent does not expressly state that less than 50%, 45%, or 40% of glucosamine amino groups in the composition of their purified PS/A polysaccharide are substituted with acetate, although the patent taught that the extent of acetylation of the PS/A (poly beta-1,6-glucosamine) varies depending on the growth conditions.

However, it was routine and conventional in the art of acetylated staphylococcal polysaccharides to deacetylate an acetylated staphylococcal polysaccharide to study or determine the presence of immunological determinants therein. For example, Fattom *et al.* taught deacetylation of a highly acetylated staphylococcal polysaccharide by incubation at 37°C with NaOH to produce the polysaccharide backbone before using the backbone (i.e., the deacetylated polysaccharide) to determine the presence of backbone immunodeterminants. See abstract; and pages 4588 and 4591.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to deacetylate the '828 patent's acetylated poly beta-1,6-glucosamine to produce the instant invention with a reasonable expectation of success. Given that it was routine and conventional in the art to deacetylate an acetylated staphylococcal polysaccharide to make available or expose the immunodeterminants on the polysaccharide backbone as taught by Fattom *et al.*, one of ordinary skill in the art would have been motivated to produce the instant invention for the expected benefit of identifying the immunodeterminants on the backbone of the '828 patent's acetylated poly beta-1,6-glucosamine PS/A.

Claims 1, 2, 4-25, 42 and 86-98 are *prima facie* obvious over the prior art of record.

Remarks

29) Claims 1, 2, 4-25, 42 and 86-98 stand rejected.

30) Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. **THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 C.F.R 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

31) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. The Fax number for submission of amendments, responses and/or papers is (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

32) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.Mov. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

33) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571)

272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Shanon Foley, can be reached on (571) 272-0898.

/S. Devi/
S. Devi, Ph.D.
Primary Examiner
AU 1645